



MAY 15 2001

Sunrise Home Healthcare Group
Mobility Products Division
7477 A East Dry Creek Parkway
Longmont, CO 80503
Tel: (303) 218-4500
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510(k) SUMMARY

Submitter's Name and Address

Sunrise Medical
7477 East Dry Creek Parkway
Longmont, Colorado 80503
Phone (303) 218-4500
Fax (303) 218-4793

Contact Person: John Gerhold, Vice President of QA/RA

Date Prepared: April 25, 2001

Device Trade or Proprietary Name

Sunrise Medical Breezy 300 Manual Wheelchair

Device Common or Usual of Classification Name

Mechanical Wheelchair

Identification of predicate device

Sunrise Medical Breezy 510 Manual Wheelchair (k974820)

Description of the device

The Breezy series wheelchairs are lightweight manual chairs. These chairs are intended to provide mobility based on an individual user's needs and capabilities. They allow fit to a particular user, and adjustable in various ways.

Breezy wheelchairs consists of typical components found on most wheelchairs, such as backrest, seat frame, cushion, footrest and casters. Accessories can include items such as armrests, positioning belts, backpacks, seat pouches, oxygen tank holders, IV poles, etc.

Many of these components may become available in a range of sizes, shapes, angles, forms, materials or coverings. These variations allow the chairs to be configured to meet the specific desires and needs of the user.

The chairs have excellent performance indoors and are very good outdoors over surfaces that are firm and free of large obstacles and long steep inclines. That makes them an ideal maneuverable, lightweight.

Warnings, cautions and contraindications are detailed in the user's manual.

Intended use

Breezy wheelchairs empower physically challenged persons by providing a means of enhanced mobility.

Comparison of device characteristics to predicate

This device (Sunrise Medical Breezy 300 Manual Wheelchair) has similar characteristics as the predicated device (Sunrise Medical Breezy 510 Manual Wheelchair). They use similar materials in their frame and components, and standard materials and covers for the slings and backs. The operating characteristics and maneuverability are equivalent, and recommended for indoor or outdoor use. Standard accessories and components are common.

Non-Clinical Testing

This device has been tested to ANSI/RESNA Wheelchair Standards. They include:

ANSI/RESNA W/C 1	Determination of Static Stability
ANSI/RESNA W/C 5	Determination of Overall Dimensions, Mass and Turning Space
ANSI/RESNA W/C 7	Method of Measurement of Seating and Wheel Dimensions
ANSI/RESNA W/C 8	Static Impact and Fatigue Strength Test
ANSI/RESNA W/C 15	Documentation and Labeling
ANSI/RESNA W/C 16	Flammability

Conclusion

Analysis of comparison of design, function and features of the Sunrise Medical Breezy 300 Manual Wheelchair to the Sunrise Medical Breezy 510 Manual Wheelchair, together with the results of compliance testing to existing ANSI/RESNA, demonstrates the device to be substantially equivalent to the predicate in terms of meeting performance criteria and functioning as intended.

The Breezy 300 Wheelchair is substantially equivalent to the predicated device listed in this 510(k) and does not raise any issues of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2001

Mr. John Gerhold
Vice President of QA/RA
Sunrise Medical, Inc.
7477 East Dry Creek Parkway
Longmont, Colorado 80503

Re: K011268
Trade Name: Breezy Wheelchair Model 300
Regulation Number: 890.3850
Regulatory Class: I
Product Code: IOR
Dated: April 25, 2001
Received: April 26, 2001

Dear Mr. Gerhold:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K011268

Indications for Use

Breezy manual wheelchairs empower physically challenged persons by providing a means of mobility.

510(k) number: Not assigned as of this time

Device name: Breezy 300 Manual Wheelchair

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tom Hallows for CDRH
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011268

Prescription use (per 21 CFR801.109)

Over-the-counter use